DETAILED ACTION

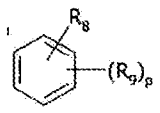
Status of the claims: Claims 40-58 currently pending. Applicant cancelled all previously pending claims and introduced new claims 40-58.

Priority: This application is a 371 of PCT/EP04/14847 (12/15/2004) and claims foreign priority to EUROPEAN PATENT OFFICE (EPO) 03 293 152.9 (12/15/2003) and EUROPEAN PATENT OFFICE (EPO) 04 292 681.6 (11/12/2004).

IDS: The IDS dated 4/5/10, 4/6/10, 4/8/10 were considered.

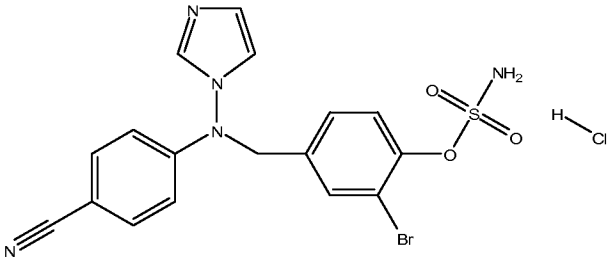
132 Declaration: The declaration of Jacqueline Shields under 37 CFR 1.132 filed 4/5/10 is sufficient to overcome the obviousness rejection of the claims; however, since applicant has cancelled the claims, the specific issue is rendered moot. Nevertheless, the declaration describes experimental data allegedly showing that the compounds of the instant invention show an "unexpected higher aromatase activity and sulfatase activity" over an otherwise identical compound of the prior art (but for the triazole core). Furthermore, the declaration concludes by describing why the declarant believes the Wermuth prior art references teaching of isosteric ring changes would not result in a reasonable expectation of success in replacing the triazole ring with an imidazole ring.

Election/Restrictions

1. Applicant's election with traverse of a Group I (claims 1-31 where Z is ) in the reply filed on 7/9/09 and 4/29/09 is acknowledged. The traversal is on the ground(s) that unity of invention was applied improperly. This is not found persuasive because the claims do not share a substantial structural feature that is

essential to the utility nor is it a contribution over the prior. The lack of unity of invention is further evidenced by the fact that the non-variable common structural feature is known in the prior art as cited in the requirement for restriction and as described in the following rejection.

The requirement is still deemed proper and is therefore made FINAL. Application also elected the following species (example 45 allegedly reading on claims 11-14; interpreted by the examiner to read on claims 1-14):



, which reads on the instant claims when:

R1, R2, R4 = H,

R3 = CN,

R8/9 = -Br / -S(O2)-NH2

p=1

Q = CH2.

As detailed in the following rejections, the generic claim encompassing the elected species was not found patentable. Therefore, the provisional election of species is given effect, the examination is restricted to the elected species only, and claims not reading on the elected species are held withdrawn.

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection through amendment, the amended Markush-type claim will be

reexamined to the extent necessary to determine patentability of the Markush-type claim. See MPEP 803.02.

RESPONSE TO APPLICANT REMARKS

Claim Rejections - 35 USC § 112

2. Claims 1-14 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant cancelled the claims, therefore, this rejection is rendered **moot**.

3. Claims 1-14 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while potentially being enabling for the compounds identified as having inhibitory effect with experimental data, does not reasonably provide enablement for the asserted utility of the entirety of the claim scope. Applicant cancelled the claims, therefore, this rejection is rendered **moot**.

Claim Rejections - 35 USC § 103

4. Claims 1-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 5,674,886) in view of Wermuth (C. Wermuth, Editor, Practice of Medicinal Chemistry, Academic Press (1996), pp. 203–237), Strehlke et al. (US 5,045,558), Bowman et al. (US 4,978,672), and Bowman et al. (US 4,937,250). Applicant cancelled the claims, therefore, this rejection is rendered **moot**.

Double Patenting

5. Claims 1-14 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,737,433. Applicant cancelled the claims, therefore, this rejection is rendered **moot**.

NEW CLAIM REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 102

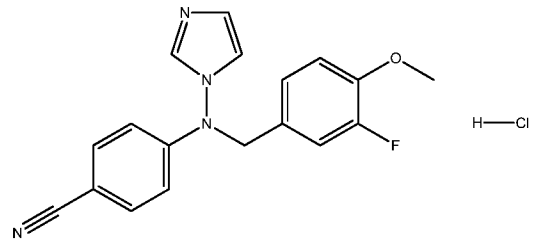
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 40, 41, 43-49, 53-55 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6737433.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The '433 patent teaches the following compound as example 9:



Benzonitrile, 4-[[(3-fluoro-4-methoxyphenyl)methyl]-1H-imidazol-1-ylamino]-, hydrochloride

This anticipates the instant claims of formula (I) when:

R1, R2, R4 = H,

R3 = CN,

R8/9 = -F / -OMe

p=1

Q = (CH2)m-X-(CH2)n-A (X and A are a direct link, n=0, m=1) => CH2

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 42 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 42 is dependent on cancelled claim 1. Thus, one of skill in the art could not reasonably determine the metes and bounds of the claims.

11. Claim 45 recites the limitation “SO2” in the definition of "Q". There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

12. Claims 50-52 and 56-58 are object to for being dependent on a rejected base claim.

Conclusion

The claims are not in condition for allowance. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626